MEMORANDUM FOR SGVT
ATTN: CAPT RYAN B SHAVER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Anticoagulation Quality Assessment in Patients with Nonvalvular Atrial Fibrillation (NVAF) and Comparison with Major Trials of Direct-Acting Oral Anticoagulants** presented at **Texas Society of Health-System Pharmacists, Alcalde, Texas 22-24 April 2016** with MDWI 41-108, and has been assigned local file #16118.

2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

*Partners in a high-performance health system, dedicated to excellence in global care*
PROCESSING OF PROFESSIONAL MEDICAL RESEARCH PUBLICATIONS/PRESENTATIONS

TO: Clinical Research Division/SGVU (59 MDW/SGVU)
FROM: Author's Name. Rank, Grade, Office Symbol Ryan B Shaver, Capt, O-3, SGVPI
PROTOCOL NUMBER: C.2016.25e

PROTOCOL TITLE - [NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.]
Anticoagulation Quality Assessment in Patients with Nonvalvular Atrial Fibrillation (NVAF) and Comparison with Major Trials of Direct-Acting Oral Anticoagulants

1. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED

2. FUNDING RECEIVED FOR THIS STUDY? □ YES □ NO FUNDING SOURCE:

3. IS THIS MATERIAL CLASSIFIED? □ YES □ NO

4. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? □ YES □ NO

5. MATERIAL IS FOR (Check appropriate box or boxes for approval with this request.) □ DOMESTIC RELEASE □ FOREIGN RELEASE

□ PUBLICATION/JOURNAL (List intended publication/journal)

□ PUBLICATION ABSTRACT (List intended journal.)

□ POSTER (To be demonstrated at meeting/Name of Meeting, City, State, and Date of Meeting)

□ PLATFORM PRESENTATION (At civilian institutions/Name of Meeting, State, Date of Meeting)
Texas Society of Health-System Pharmacists/ALCALDE/Texas/April 22-24

□ OTHER (Describe: Name of Meeting, City, State, and Date of Meeting)

6. WHAT IS THE EXPECTED DATE YOUR PRESENTATION/PUBLICATION WILL BE SUBMITTED TO THE DEFENSE TECHNICAL INFORMATION CENTER (DTIC)? Apr 1, 2016

POINT OF CONTACT

7. WHO IS THE PRIMARY 59 MDW POINT OF CONTACT? (Last, First, Mi.) (Include email) DUTY PHONE/PAGER No. Fenzi, Heather, W. Major, heather.fenzi@us.army.mil 210-916-7633

AUTHORSHIP AND CO-AUTHOR(S) (List in the order they will appear in the manuscript)

LAST NAME, FIRST NAME AND MI. GRAD/RANK SQUADRON/GROUP/OFFICE SYM INSTITUTION (If not 59 MDW)
a. Primary/corresponding author Ryan B Shaver Capt 959 CSPS/SGVPI
b. R. Scott Holub CIV 959 CSPS/SGVPI
c. Thoma C Shank CIV 959 CSPS/SGVPI
d.
e.
f.
g.

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP AND 69 MDW 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

AUTHOR'S PRINTED NAME/RANK/GRADE Ryan B Shaver, Capt

AUTHOR'S SIGNATURE SHAVER,Ryan,B.1392237190

APPROVING AUTHORITY’S PRINTED NAME, RANK, TITLE Fenzi, Heather, Maj, USAF, BSC Associate Program Director Pharmacy Practice Residency

APPROVING AUTHORITY’S SIGNATURE FENZI,HEATHER,WINFREE,12639938352

DATE Mar 3, 2016

DATE Mar 4, 2016

59 MDW Form 3039 (DATE) Supersedes 59 MDW Form 3039, 201311018
### PROCESSING OF PROFESSIONAL MEDICAL RESEARCH PUBLICATIONS/PRESENTATIONS

**1st INDOREMENT (SGVU Use Only)**

| TO: Clinical Research Division  
| Contact 292-7141 for email instructions | 1. DATE RECEIVED | 2. ASSIGNED PROCESSING REQUEST FILE NUMBER | 3. DATE REVIEWED | 4. DATE FORWARD TO PA |
| 59 MDW/SGVU | 3/7/2016 | 16118 | 8 Mar 2016 |  |

5. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES

- [x] NO  
- [ ] YES  
- [ ] N/A  
- [ ] If yes give date:

6. COMMENTS

- [x] APPROVED  
- [ ] DISAPPROVED  

The article is approved.

**PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER**  
Rocky Calcote, PhD  
Clinical Research Administrator

**DATE**  
**SIGNATURE OF REVIEWER**  
CALCOTE.ROCKY.D.1178245844

**2nd INDOREMENT (PA Use Only)**

| TO: 59 MDW OFFICE OF PUBLIC AFFAIRS  
| PA | 1. DATE RECEIVED | 2. DATE FORWARD TO 59 MDW/SGVU |
| 59 MDW/SGVU | Mar 15, 2016 | Mar 17, 2016 |

6. COMMENTS  
- [x] APPROVED (In compliance with security and policy review directives.)  
- [ ] DISAPPROVED  

PA corrected "San Antonio Military Medication Center" (METHODS) to read "San Antonio Military Medical Center".

**PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER**  
Christopher Carwile, TSgt/E-6, NCOIC, PA

**DATE**  
**SIGNATURE OF REVIEWER**  
CARWILE.CHristOPHERS.Tewart.1280477229

**3rd INDOREMENT (SGVU Use Only)**

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<th>TO: 59 MDW/SGVU</th>
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2. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL:  
- [x] YES  
- [ ] NO  
- [ ] Could not be reached  
- [ ] Left message  

3. DATE WRITTEN NOTICE OF APPROVAL AND CLEARANCE MAILED TO AUTHOR:  

4. COMMENTS  
- [ ] APPROVED  
- [ ] DISAPPROVED

**PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER**  
**SIGNATURE OF REVIEWER**  
**DATE**

59 MDW Form 3039 (DATE)  
Supersedes 59 MDW Form 3039, 20131018  
Page 3 of 3
ANTICOAGULATION QUALITY ASSESSMENT IN PATIENTS WITH NONVALVULAR ATRIAL FIBRILLATION (NVAF) AND COMPARISON WITH MAJOR TRIALS OF DIRECT-ACTING ORAL ANTICOAGULANTS (DOACs). Ryan B Shaver, R. Scott Holub, Thomas C Shank, San Antonio Military Medical Center, San Antonio, TX; Pfizer Inc., San Antonio, TX.

PURPOSE: The benefits of warfarin anticoagulation therapy are strongly correlated with the ability to maintain patients’ INR goal, known as the time in therapeutic range (TTR). TTR is reported as a percentage and there are three commonly used calculation methods (traditional, cross sectional, and Rosendaal). Differences in TTR calculations could alter perceptions about the effectiveness of warfarin therapy.

METHODS: At San Antonio Military Medical Center (SAMMC), we conducted a retrospective study to review of medical records. 312 patients with non-valvular atrial fibrillation (NVAF) on warfarin therapy who had an INR goal of 2-3 were identified. TTR was calculated using the three different methods. The primary end point was difference in calculated TTR in the SAMMC Anticoagulation Clinic (ACC) population.

RESULTS: INR data were collected for all warfarin-treated NVAF patients seen in the ACC from 5 Jan to 30 Dec 2015. A total of 5580 INR values for 312 patients were included in the analysis. The mean (SD) for patient-level TTRs using the traditional and Rosendaal methods were 68.5% (66.6-70.4) and 72.4% (70.2-74.6), respectively. Comparing the results using the paired t-test resulted in a significant difference between methods (p < 0.0001). The cross sectional method produced a TTR of 74.4%. All published DOAC trials used the Rosendaal method to measure TTR. The mean (SD) for the Rosendaal TTRs at SAMMC and published in the ENGAGE-AF TIMI trial were 72.4% (19.6) and 64.9% (18.7) respectively; these means were significantly different (p < 0.001). Since the SD was not reported for the other three DOAC trials (ARISTOTLE, RE-LY, and ROCKET-AF), comparing the confidence intervals of these trials showed no overlap with SAMMC’s ACC.

CONCLUSIONS: For patients treated at SAMMC’s ACC, there was a significant difference between the Rosendaal TTR and traditional TTR and between the traditional TTR and the cross sectional TTR. There was no apparent difference between the cross sectional and Rosendaal TTRs. Although significant differences were seen in two of the three TTR comparisons, this alone does not suggest which method of calculation was most accurate. Each method has strengths and limitations and all three methods should be used to help determine the effectiveness of an ACC. The ENGAGE-AF TIMI has the highest TTR of the DOAC trials and was closest in value to our patient population, yet the TTR was still significantly lower than that calculated for our patients. This raises the question whether the effectiveness of the DOACs in their major trials can be directly compared (i.e. have equal effectiveness) to a patient population with a greater TTR. Further research looking at outcomes in our patients may be warranted. Patients should be thoroughly evaluated for potential benefits, and with an understanding of the generalizability of the DOAC trials, when switching anticoagulation therapy.

BAMC PAO has reviewed the following journal and finds one observation: “The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, the Department of the Air Force and Department of Defense or the U.S. Government.”
MEMORANDUM FOR 59 MDW
ATTN: CAPT RYAN B. SHAVER

FROM: 502 ISG/JA

SUBJECT: Ethics Review for Presentation Approval Request (Shaver)

1. Capt Shaver submitted a request for a legal review of an abstract titled “Anticoagulation Quality Assessment in Patients with Nonvalvular Atrial Fibrillation (NVAF) and Comparison with Major Trials of Direct-Acting Oral Anticoagulants (DOACs)” The author plans to present this research as a platform presentation at the Texas Society of Health-System Pharmacists/ALCALDE in Frisco, Texas on 22-24 April 2016. This legal review is limited to the ethics issues regarding the presentation. The abstract contains the required disclaimer discussed below. The abstract must also be submitted for Public Affairs approval. There are no conflict of interest issues with presenting this research at this professional society meeting.

2. FACTS: Capt Shaver plans to present his abstract titled “Anticoagulation Quality Assessment in Patients with Nonvalvular Atrial Fibrillation (NVAF) and Comparison with Major Trials of Direct-Acting Oral Anticoagulants (DOACs)” at the Texas Society of Health-System Pharmacists 2016 Annual Seminar in Frisco, Texas on 22-24 April 2016.

3. LAWS AND REGULATIONS: DoD 5500.07-R, Joint Ethics Regulation (JER), section 3-305 lays out rules governing “Teaching, Speaking and Writing.” If the presentation will “deal in significant part with any ongoing or announced policy, program or operation” of the Air Force, the presenter is required to include a disclaimer that states the “views presented are those of the speaker or author and do not necessarily represent the views of DoD or its Components.”

4. ANALYSIS: The presentation does not “deal in significant part with any ongoing or announced policy, program or operation” of the Air Force, however, the abstract does address research done as part of the author’s military medical practice. Additionally, the presenter’s affiliation with the military will presumably be included as part of the presentation. Therefore, the author has included the required disclaimer that the views presented are those of the authors and do not necessarily represent the views of DoD or its Components on the slide presentation. Although the disclaimer language included on the presentation is not verbatim from the JER, the language used is appropriate and clearly captures the intent of the language used in the JER. There are no apparent conflicts of interest that would prohibit the presentation.

5. CONCLUSIONS: The abstract presented for review included the disclaimer required by the JER. There are no conflicts of interest.
6. If you have any questions, please call me at 210-671-5771.

[Signature]
VERNISHA N. FOSTER, Captain, USAF
Assistant Staff Judge Advocate

I concur.

[Signature]
MARK E. COON, Major, USAF
Acting Chief, Civil Law